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Dated 16 November 1999

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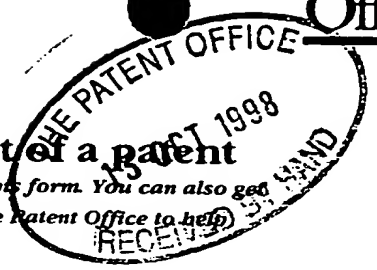

1/77

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
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1. Your reference

DCW/VSW

2. Patent application number
(The Patent Office will fill in this part)

13 OCT 1998 9822341.5

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

KCI MEDICAL LIMITED
Two Rivers
Station Lane
Witney
Oxfordshire OX8 6BH

Patents ADP number *(if you know it)* 6989628001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

"Negative Pressure Therapy Using Wall Suction"

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Brookes & Martin

High Holborn House
52/54 High Holborn
London WC1V 6SE

Patents ADP number *(if you know it)* 471001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

yes

9. Enter the number of sheets [redacted] any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	7
Claim(s)	2
Abstract	
Drawing(s)	3 +3

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 14/10/1998
BROOKES & MARTIN

12. Name and daytime telephone number of person to contact in the United Kingdom 0171 242 9631 - David C. Woodcraft

Warning

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Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.

b) Write your answers in capital letters using black ink or you may type them.

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d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.

e) Once you have filled in the form you must remember to sign and date it.

f) For details of the fee and ways to pay please contact the Patent Office.

NEGATIVE PRESSURE THERAPY USING WALL SUCTION

This invention relates to negative pressure therapy and provides a device which can be used to provide such therapy on connection to an existing source of suction, such as a vacuum line.

Our prior patent application WO 97/18007 describes portable wound treatment apparatus for stimulating the healing of wounds. The apparatus described in our above application comprises a porous pad, which is permeable to fluids, for packing into or over the wound, dressings for covering and for providing an air-tight seal around the wound, and a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, a canister being provided for collecting fluids which are sucked from the wound.

The apparatus described in our above application can be worn by the patient on a harness or sling so that he is not confined to one particular place while the therapy is in progress. There is, however, a demand for a more basic piece of equipment which, although not as sophisticated as the equipment described in our above application, does provide some of the benefits of negative pressure therapy.

Most hospitals have a suction line which is fed to all the wards and is available to nursing staff for a variety of purposes, such as powering drainage tubes and suctioning body fluids generally. For such uses, a pressure regulator may be connected to the source of suction and this regulator may include a pressure gauge indicating the pressure at the regulator valve. It is, however, dangerous to connect such a suction source directly with a patient, without providing continuous

supervision. In many hospitals, shortage of staff makes it difficult or impossible to provide adequate close supervision, and if attempts are made to use such a source for negative pressure therapy, there is a very real danger of injuring the patient.

An object of the present invention is to provide equipment which can be used with an existing wall suction source to safely provide negative therapy to patients.

According to one aspect of the present invention there is provided apparatus for applying negative pressure therapy to a wound site, said apparatus comprising an open celled foam pad for application to the wound, a suction tube connecting the foam pad to a collection canister, said canister having a shut-off valve which closes the outlet from the canister when it is full, a tube for connecting the canister to a wall suction point and a pressure detecting means connected to the suction tube between the foam pad and the canister for indicating when the pressure in the suction tube falls below a predetermined level. The pressure detecting means may be a transducer which is connected by a branch tube to the suction tube leading from the foam pad to the canister. The transducer may be set to generate a visible and/or audible warning when the pressure in the suction tube falls below a pre-set level. A sudden pressure drop in the suction line would indicate that the canister is full and, consequently, there is no longer any effective therapy being applied to the therapy.

The canister full situation would normally be indicated by substantially zero pressure in the suction line. The transducer may also be set to activate a warning in the event that the pressure in the suction line does not reach a minimum pre-set

pressure, or the pressure rises towards atmospheric after suction has initially been established, thereby indicating a gross leak in the system.

Preferably, the apparatus also includes a flow limiter in the line connecting the canister to the wall suction source so as to prevent the flow in the suction tube exceeding a pre-set level.

The apparatus may include a display panel which indicate the pressure existing at any one moment in the suction line. The transducer may also be adjustable so that indication or warning is given at different pre-set pressures.

The apparatus as described above may be adapted to give intermittent pressure therapy by providing a relief valve in a tube leading from the suction line. This relief valve may be programmable by a processor so that it is openable and closeable according to a pre-set programme thereby providing intermittent negative pressure therapy to the wound site.

Further features described below may also be introduced into the apparatus as described to give further desirable features.

Several embodiments in accordance with the invention will now be described with reference to the accompanying drawings, in which:-

Figure 1 is a diagrammatic representation of one embodiment in accordance with the invention;

Figure 2 is a diagrammatic representation of a second embodiment; and

Figures 3A & 3B are diagrammatic representations of a collection canister for monitoring rates of flow of fluids sucked from the wound.

Referring to Figure 1 of the drawings, the apparatus for applying negative therapy comprises a foam pad (1) which is applied over or packed into a wound to be treated and is connected by a suction tube (2) to a canister (3). The canister (3) may be of conventional design having a shut-off valve which automatically closes once the canister is full. A suitable canister of this kind is described in our above cited patent application or in European Patent Application No. 0358302. The canister is also connected via a further tube (4) to a pressure regulator (5). The pressure regulator carries a gauge (6) and is connected to an existing vacuum line such as a standard hospital wall suction source (7). In many hospital installations a regulator valve (5), together with a pressure gauge (6) already exist, attached to an existing suction source or can be fitted to an existing outlet in the suction source supply. The apparatus may also include an optional flow limiter (8), which may be adjusted to provide different desired levels of flow in the system.

Pressure in the suction tube (2) is measured by a branch tube (9) which is connected to the suction tube and to a transducer (10). The transducer (10) is mounted on a process control board (12) and this may be connected to a visual display (13). An optional relief valve (11) may also be connected into the tube (9) and provide a means for controlling the level of negative pressure at the wound site. The relief valve (11) may be manually settable so that the pressure at the wound site does not exceed a predetermined figure. In a more esoteric version, the relief valve may be electronically controlled from the PCB to relieve pressure at the wound site at pre-settable maximum pressures. Many hospitals, in addition to having a suction source

and a pressure regulator such as regulator (5), also have body fluid collection canisters (3) supplied for other purposes. It may, therefore, be possible to supply to the hospital apparatus included in the dotted line shown in Figure 1, together with foams and connecting tubes so that they can connect the existing apparatus to a canister and a regulator (5) available in the hospital.

A more elaborate system is shown in Figure 2, which is similar to the arrangement shown in Figure 1 except for the following features described below. The same reference numerals indicate features common to both embodiments. First, the pressure regulator 15 connecting the apparatus to the wall suction source 17 is electronically controlled by the process control board (12). Secondly, the pressure at the wound site is monitored by a transducer (20), while the pressure in the tube connecting the canister to the regulator is measured by a transducer (21). The transducer (20) is connected to the wound side by a tube (23). Instead of providing separate tubes (2) and (23), a single bi- or multi-lumen tube may be used as described in our co-pending application WO97/18007. A relief valve (24) communicates with the tube (23) and enables the apparatus to operate intermittently in a controllable manner by intermittently reducing flow through the regulator (8) and venting pressure through the valve (11). The canister full situation is detected by noting a pressure differential between transducer (20) and transducer (21), or by means of a separate fluid level sensor. Pressure detection at the wound site via the transducer (20) also indicates whether there is a pressure leak or no therapy. A custom-made canister (32) may include means for sensing electronically when the canister is full and must be

replaced, e.g. by capacitance measuring means (34). Preferably, the canister is designed to fit into a recess in a custom made housing (30), indicated by dotted lines. The housing may be directly connected at one end to the wall suction point (7), and at the other to a tube or tubes leading to the foam pad (1) at the wound site.

In the embodiment of Figure 2, the transducers (20 & 21), the relief valve (11) and pressure regulator (8) are preferably all electronically controlled by connections to the PCB. For example, the canister full situation is detected by comparison of the pressure difference between transducers (20 & 21) and this can be signalled on the display (13) and, optionally, also by an audible warning signal.

It may be desirable to measure the rate at which fluids are sucked from the wound site. This is conveniently achieved by measuring the rate at which the canister is filled with wound exudate. A suitable device is shown diagrammatically in Figure 3. In one configuration shown in Figure 3A, a sleeve (33) is held in intimate contact with the outer surface of the canister. This sleeve carries a single sensing element (35), e.g. capacitive sensor that can provide a means of sensing the presence of liquid at different levels in the canister by simply moving the sleeve up and down the canister. The sensing element detects the presence of liquid by projecting an electrical field into the canister and detecting any change in that field, e.g. by a change in capacitance. The rate of change of capacity over the portion of the canister surveyed by the detector gives an indication of rate of flow of fluid sucked from the wound site.

In another configuration shown in Figure 3B, a series of sensing elements (36) are evenly spaced on a sleeve (33) that is in contact with the outer surface of the

canister. As the fluid level rises within the canister, the sensing elements are triggered. This information can then be used by the control system at the PCB to deduce flow rate.

CLAIMS:-

1. Apparatus for applying negative pressure therapy to a wound site, which comprises an open celled foam pad for application to the wound, a suction tube connecting the foam pad to a collection canister, said canister having a shut-off valve which closes the outlet from the canister when it is full, a tube for connecting the canister to a wall suction point and a pressure detecting means connected to the suction tube between the foam pad and the canister for indicating when the pressure in the suction tube falls below a predetermined level.

2. Apparatus as claimed in claim 1 which includes a flow limiting valve disposed between the canister and the suction source.

3. Apparatus as claimed in claim 1 or 2 which includes a pressure relief valve which is connected to the suction tube between the foam pad and the canister.

4. A modification of the apparatus as claimed in any one of the preceding claims which includes a first transducer for measuring pressure in a tube linking the canister to the wall suction point, and a second transducer for measuring pressure at the wound site.

5. Apparatus as claimed in any one of the preceding claims which includes flow rate measuring means for measuring the rate at which fluid is sucked from the wound site.

6. Apparatus as claimed in claim 6 in which the flow rate measuring means comprises a device for measuring the rate at which the canister is filled.

7. Apparatus as claimed in claim 6 in which the flow rate measuring means is an electrical capacitance measuring device.

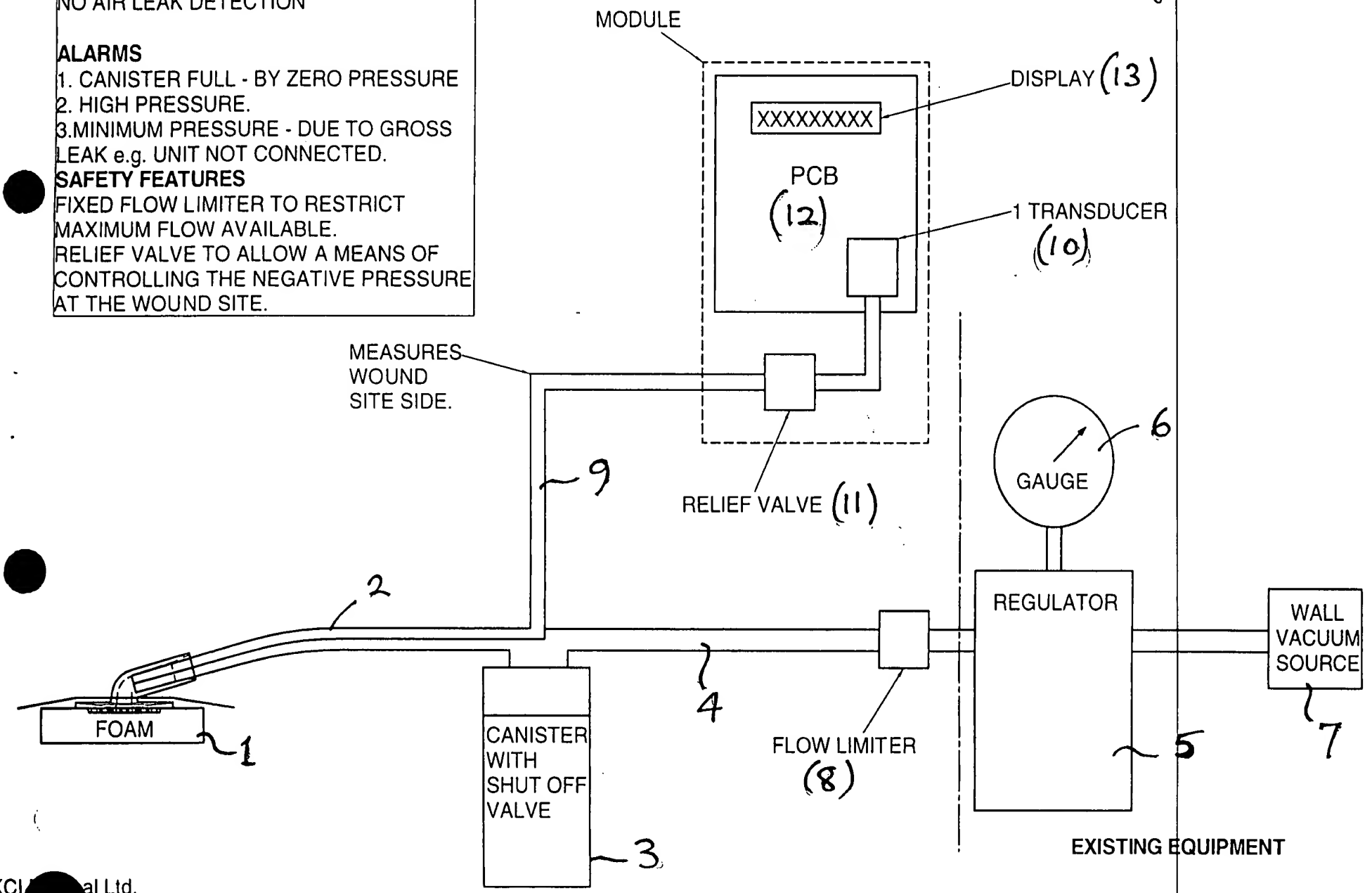
WALL SUCTION NEGATIVE PRESSURE REGULATOR SCHEMATIC - BASIC MODEL V1b

Figure 1

NO INTERMITTENT THERAPY
NO AIR LEAK DETECTION

ALARMS
1. CANISTER FULL - BY ZERO PRESSURE
2. HIGH PRESSURE.
3.MINIMUM PRESSURE - DUE TO GROSS LEAK e.g. UNIT NOT CONNECTED.

SAFETY FEATURES
FIXED FLOW LIMITER TO RESTRICT MAXIMUM FLOW AVAILABLE.
RELIEF VALVE TO ALLOW A MEANS OF CONTROLLING THE NEGATIVE PRESSURE AT THE WOUND SITE.



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WALL SUCTION NEGATIVE PRESSURE REGULATOR SCHEMATIC - MODEL V2

Figure 2

FEATURES

CANISTER FULL -
1 PRESSURE DIFERENTIAL BETWEEN
TRANSDUCER 1 AND TRANSDUCER 2
OR
2. FLUID LEVEL SENSOR.

MAXIMUM PRESSURE LIMITER
AIR LEAK DETECTION
MINIMUM PRESSURE DETECTED - I.E. NO THERAPY
INTERMITTENT THERAPY.

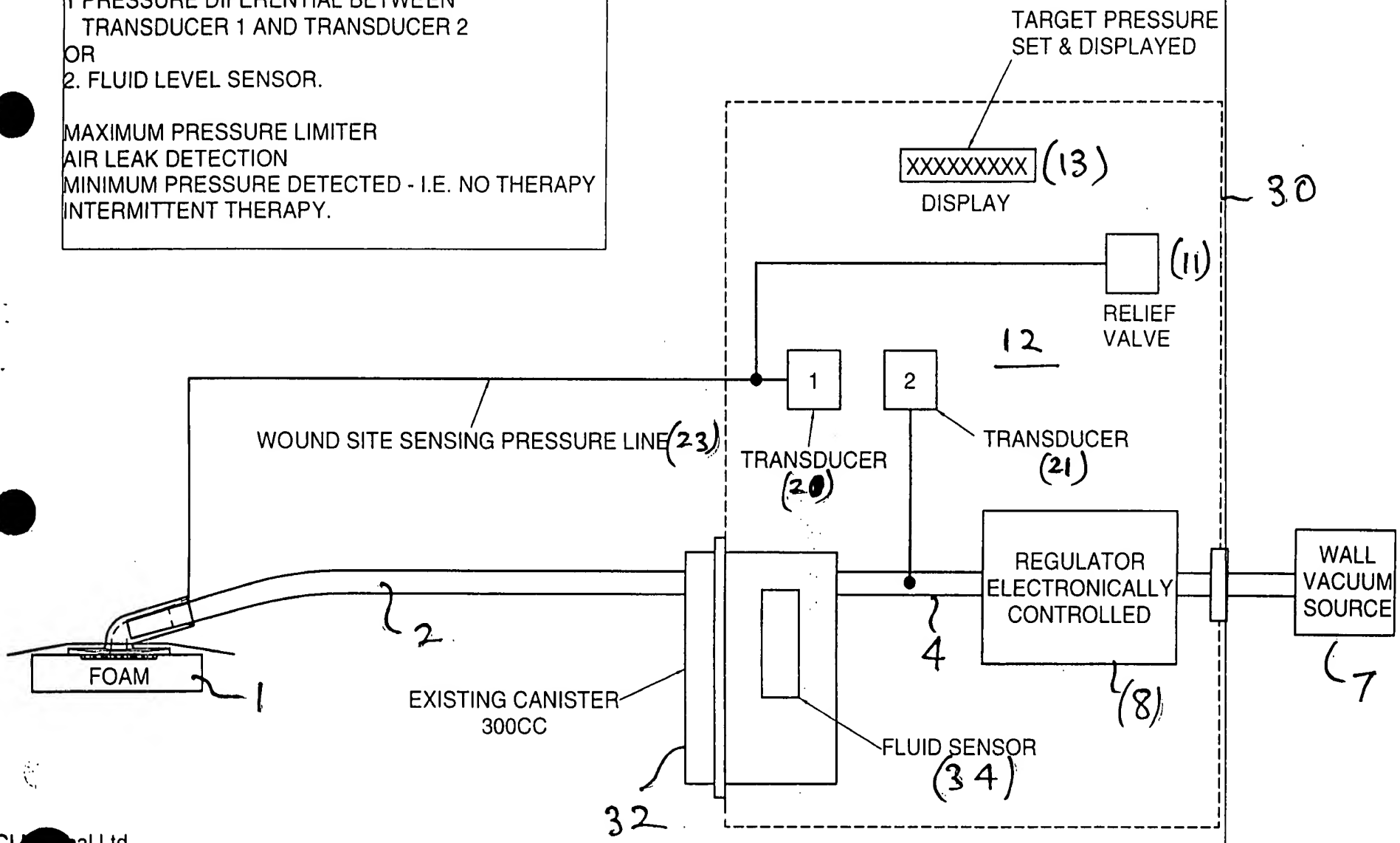

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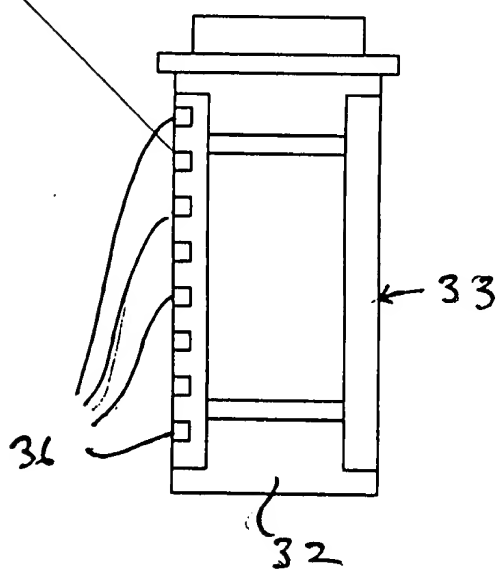
Fig 3B

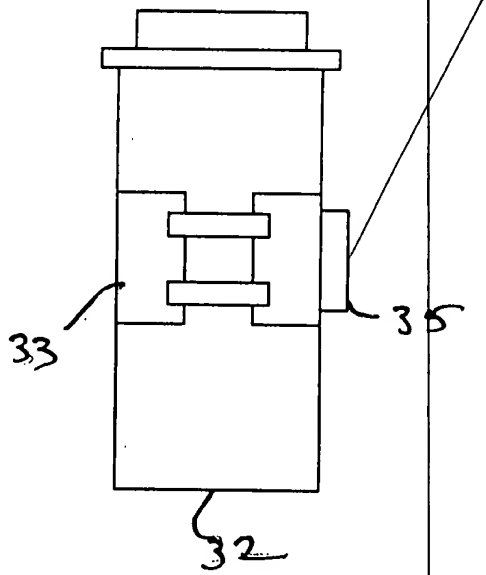
STRAP ON MULTIPLE
CAPACITANCE STRAP.
USED TO MEASURE
FLUID RATE



STANDARD CANISTER

Fig 3A

STRAP ON MULTIPLE
CAPACITANCE SENSOR
SET AT SINGLE LEVEL.



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